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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,162	01/31/2002	David M. Harris	HARRIS-00101	2707

28960 7590 09/22/2005

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EXAMINER

ROANE, AARON F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,162

Applicant(s)

HARRIS, DAVID M.

Examiner

Aaron Roane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20, 21, 23-32, 43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 20, 21 and 23-32 is/are allowed.
- 6) ☒ Claim(s) 1-18, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9-11, 13-16, 18, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rechmann (USPN 5,795,153) in view of Ward et al. (USPN 6,506,563 B1).

Regarding claims 1, 3, 18, 43 and 44, Rechmann disclose a method (and a device) for removing (i.e., eradicating) bacterial deposits from teeth comprising locating the pathogens within the oral cavity (inherently part of treatment) and radiating periodontal tissue of the oral cavity with a succession of pulses from a pulsed laser having an energy density of 10 J/cm² or greater per pulse, see abstract, col. 2, lines 19-67, col. 5, line 32 through col. 6, line 57 and figures 1 and 2. **Rechmann also discloses selecting a pulsed laser light with a wavelength corresponding to an absorption spectrum of the pathogen, see col. 2, lines 19-28.** Rechmann fails to explicitly recite that testing for the presence of one or more pathogens within the oral cavity is performed with a culture. Ward et al. disclose teach that it is well known in the art that the treatment of periodontal

tissue traditionally includes the identification of pathogens (and thus the inherent testing for) via the use of cultures, see col. 40, lines 8-24. Additionally, the examiner takes official notice of the recitation of pulsed laser light penetrates into the target tissue to a distance of 1.0 mm or greater, since 1) given the various parameters of the laser source (i.e., wavelength, power, etc.) the laser light inherently penetrates the target tissue to a distance of 1.0 mm or greater and 2) it is well known in the art that laser light (having a range of various parameter) penetrates target tissue to and/or beyond the depth of 1.0 mm. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Rechmann, as is well known in the art as shown by Ward et al., to traditionally identify pathogens (and thus the inherent testing for) via the use of cultures when treating periodontal tissue.

Regarding claim 2, Rechmann further discloses an operating wavelength of 300 nm to 600 nm, see col. 2, lines 19-27.

Regarding claim 4, Rechmann discloses the claimed invention. Inherently the treatment involves tissue volumes.

Regarding claim 5, Rechmann further discloses the treatment a periodontal pocket, see figure 1.

Regarding claims 6 and 7, Rechmann further discloses that this treatment takes place via the use of an optical fiber (26) wherein the distal end of the optical fiber is located in the periodontal pocket, see col. 7, lines 20-32 and figures 5-7.

Regarding claims 9 and 10, Rechmann discloses the claimed invention. The maximum fluence, Flu_{max} of the pulsed laser light is equal to the maximum pulse repetition frequency, f_{max} , times the maximum energy density per pulse, **Density**, times the length of time irradiation, $T_{radiation}$ which is given by, $Flu_{max} = f_{max} \times \text{Density} \times T_{radiation}$. This equals 600 J/cm^2 for only three seconds of irradiation, see col. 2. Additionally, Rechmann discloses that a “gingival pocket (6)” has a size or depth of “0.5 to 2 mm,” see col. 4, lines 27-39. The examiner estimates the size of the periodontal pocket area irradiated to be roughly from 0.25 to 4 mm^2 and therefore by simply multiplying the above fluence of 600 J/cm^2 times the irradiated periodontal pocket area of multiplying the 4 mm^2 , this yields an absorption of 2.4 Joules which meets the further limitation of claim 10.

Regarding claim 11, Rechmann discloses the claimed invention. The pulsed laser has pulse widths of 50 nanoseconds (ns) to 300 ns, see col. 2, lines 51-56. The pulse width (or pulse length) is the time in which the laser is irradiating the tissue. Therefore, the disclosure of Rechmann meets the claimed invention.

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Regarding claims 13 and 14, Rechmann further discloses that *Prevotella intermedia* is treated, see col. 5, lines 44-56.

Regarding claim 15, Rechmann discloses the claimed invention. Rechmann disclose that “black-pigmented bacteroides” are also treated, see col. 5, lines 32-67.

Regarding claim 16, Rechmann in view of Ward et al. disclose the claimed invention except for disclosing that the pigmented fungus is selected from the group consisting of *Histoplasma* and *Aspergillus Niger*. At the time of the invention, it would have been an obvious matter of treatment optimization to one of ordinary skill in the art to also teach the pigmented fungus is selected from the group consisting of *Histoplasma* and *Aspergillus Niger* since they also cause periodontal disease and are sensitive to laser irradiation.

Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rechmann (USPN 5,795,153) in view Ward et al. (USPN 6,506,563 B1) as applied to claims 3 and 6 above, and further in view of Myers (USPN 6,019,605).

Regarding claim 8, Rechmann in view of Ward et al. disclose the claimed invention except for explicitly reciting that the diameter of the fiber optic is 0.05 mm to 3.0 mm. Myers discloses a device having a laser and fiber optic and method for treating periodontal disease and teach that “ in order to treat the periodontal disease, a free end 18 of an optical fiber 20 is inserted into the periodontal pocket. The optical fiber preferably

has a diameter of between 300 and 600 microns,” see col. 2, lines 33-36. 1 million microns equals 1 meter, or 100 centimeters or 1000 millimeters, therefore Myers discloses a fiber optic that has a diameter range of 0.3 mm to 0.6 mm. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Rechmann in view of Ward et al., as taught by Myers, to use a fiber optic having a diameter in the range of 0.3 mm to 0.6 mm in order to treat the periodontal disease.

Regarding claim 12, Rechmann in view of Ward et al. disclose the claimed invention except for explicitly reciting that debridement is performed prior to laser irradiation. Myers teaches “debridement of the plaque from the teeth as well as diseased soft tissue in the periodontal pocket is performed in the conventional fashion. Following such debridement, however, an optical fiber is inserted into the periodontal pocket and laser radiation is emitted through the optical fiber and against not only the soft tissue but also the plaque within the periodontal pocket. For reasons not entirely understood, such laser radiation of the periodontal pocket following debridement has been found to render the periodontal pocket resistant to subsequent bacterial reinfection of the periodontal pocket,” see col. 1, lines 41-51. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Rechmann in view of Ward et al., as taught by Myers, to perform debridement prior to the irradiation of the target tissue in order “to render the periodontal pocket resistant to subsequent bacterial reinfection of the periodontal pocket.”

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rechmann (USPN 5,795,153) in view Ward et al. (USPN 6,506,563 B1) as applied to claim 1 above, and further in view of Hasan et al. (USPN 6,462,070 B1).

Regarding claim 17, Rechmann in view of Ward et al. disclose the claimed invention except for disclosing that a staining agent is used to stain the bacteria or one or more pathogens. Hasan et al. disclose a method of treating periodontal tissue using laser irradiation and teach the use of photosensitizers (a form of staining agents including methylene blue) to target pathogens, col. 1-11. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Rechmann in view of Ward et al., as taught Hasan et al., to use photosensitizers (a form of staining agents including methylene blue) to target pathogens.

Allowable Subject Matter

Claims 20, 21, 23-32 are allowed.

Response to Arguments

Applicant's arguments filed 9/2/2005 have been fully considered but they are not persuasive. Applicant has amended claim 1 with the recitation "wherein the pulsed laser light penetrates into the target tissue to a distance of 1.0 mm or greater and eradicates at least a portion of the pathogen within the target tissue. Again as stated in the rejections to claims 1 and 43, the examiner takes official notice of the recitation of pulsed laser light penetrates into the target tissue to a distance of 1.0 mm or greater, since 1) given the various parameters of the laser source (i.e., wavelength, power, etc.) the laser light inherently penetrates the target tissue to a distance of 1.0 mm or greater and 2) it is well known in the art that laser light (having a range of various parameter) penetrates target tissue to and/or beyond the depth of 1.0 mm.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. *A.R.*
September 19, 2005

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER